DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Martin Lonky
CEO and President
The Trylon Corporation
970 West 190th Street, Suite 850
Torrance, California 90502-1037

JAN 31 2005

Re: K033033
Trade/Device Name: ViziLite Blue Oral Examination Product
Regulation Number: 884.1720
Regulation Name: Gynecologic Laparoscope and Accessories
Regulatory Class: II
Product Code: MPU, EAZ
Dated: September 26, 2004
Received: September 26, 2004

Dear Dr. Lonky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K033033**

Device Name: **ViziLite Blue Oral Exam Product**

Indications for Use: **The ViziLite Blue Oral Exam Product consists of the Vizilite and ViziLite Blue Oral Lesion Identification and Marking System.**

The Vizilite (OralLite) is a chemiluminescent light source system indicated for use as an adjunct to conventional oral mucosal screening by trained health care providers for the identification, evaluation, and monitoring of oral mucosal abnormalities in a population at increased risk for oral cancer.

The ViziLite Blue Oral Lesion Identification and Marking System, is a three-component swab system which is indicated as an adjunct to the **ViziLite Test** for oral mucosa lesions, for further evaluation and monitoring of lesions by providing physical marking of lesions already differentially identified with ViziLite in a population at increased risk for oral cancer

The ViziLite Blue Oral Lesion Identification and Marking System is ***not*** being proposed for use in the initial oral mucosal examination without initial lesion identification with ViziLite. Furthermore, this **ViziLite Blue Oral Lesion Identification and Marking System is not intended to be used as an indicator of lesions warranting further study, including biopsy. Whether a lesion is marked with the dye or not should not alter the clinician's clinical behavior as dictated by the results of the ViziLite examination. The marking dye, when positive, acts as a lesion marker that allows for the removal of the ViziLite device while preserving the anatomic character of the lesion.**

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General Hospital
Infection Control, Dental Devices

510(k) Number K033033

XIII. SUMMARY OF SAFETY AND EFFECTIVENESS STATEMENT

DEVICE DESCRIPTION:

ViziLite Blue Oral Exam Kit includes the **ViziLite** used as an adjunct to visual examination of the oral mucosa with incandescent light for identification of oral mucosal abnormalities and **ViziLite Blue Oral Lesion Identification and Marking System** to further assist with the evaluation and monitoring of ViziLite-Identified oral white mucosal abnormalities in patients at increased risk for oral cancer.

The **ViziLite-Blue™ Oral Exam Kit** is a visualization system that is intended as an adjunct to conventional visual examination with incandescent light of oral mucosa and employs the same components and mechanism of action as the previously cleared **ViziLite Test Kit** (a.k.a. ViziLite Comprehensive Exam Tray **K012070** and the OralLite Test Kit, **K03995 and Acetic Acid Rinse**) and is indicated for the same patient population and intended use. The ViziLite examination light source and accessories, including the 1% Acetic Acid Rinse, have not been changed nor significantly modified for production of the ViziLite-Blue Oral Exam Kit.

The **ViziLite Blue Oral Lesion Identification and Marking System**, consists of three swab components, two swabs of 1% Acetic Acid Rinse, including a post-dye decolorizer, and one swab with a metachromatic vital tissue dye, Tolonium chloride, also called Toluidine Blue. The application of the dye to ViziLite-Identified oral white mucosal lesions in a population at increased risk for oral cancer, during clinical trials was able to assist with evaluation, monitoring, and tissue sampling and helped physically mark and stain 51% of the ViziLite-Identified white lesions to allow the health care provider to be able to visualize lesions with incandescent light.

INTENDED USE:

The ViziLite Blue Oral Exam Kit with ViziLite and The ViziLite Blue Oral Lesion Identification and Marking System are intended for use only as adjuncts to the conventional oral mucosa examination with incandescent light.

The **ViziLite** examination, using chemiluminescent light, is intended only as an adjunct to traditional oral examination by incandescent light to increase identification, evaluation, and monitoring of oral mucosal abnormalities in populations at increased risk for oral cancer.

The **ViziLite Blue Oral Lesion Identification and Marking System**, as supported by clinical trials, is an adjunct or an accessory to the ViziLite examination and assists in the further work up of ViziLite-Identified white oral mucosal lesions for patients at increased risk for oral cancer.

The ViziLite Blue Oral Lesion Identification and marking System is *not* intended to be used as an initial screening examination for identification and evaluation of oral mucosa abnormalities, nor is it intended to replace initial conventional screening under incandescent light, ViziLite examination or biopsy. The marking **system is not intended to be used as an indicator of lesions warranting further study, including biopsy. Whether a lesion is marked with the dye or not should not alter the clinician's clinical behavior as dictated by the results of the ViziLite examination. The marking dye, when positive, acts as a lesion marker that allows for the removal of the ViziLite device while preserving the anatomic character of the lesion.**

INDICATIONS FOR VIZILITE BLUE ORAL EXAM KIT:

The ViziLite Blue Oral Exam Kit consists of the Vizilite and ViziLite Blue Oral Lesion Identification and Marking System.

The Vizilite (OralLite) is a chemiluminescent light source system indicated for use as an adjunct to conventional oral mucosal screening by trained health care providers for the identification, evaluation, and monitoring of oral mucosal abnormalities in a population at increased risk for oral cancer.

The ViziLite Blue Oral Lesion Identification and Marking System, is a three-component swab system which is indicated as an adjunct to the **ViziLite Test** for oral mucosa lesions, for further evaluation and monitoring of ViziLite-Identified white lesions in a population at increased risk for oral cancer.

The ViziLite Blue Oral Lesion Identification and Marking System is **not** indicated to be used as an initial screening examination for identification and evaluation of oral mucosa abnormalities, nor is it intended to replace initial conventional screening under incandescent light and any of the clinician's best clinical judgment as to patient management. In addition, the marking **system is not intended to be used as an indicator or lesions warranting further study, including biopsy. Whether a lesion is marked with the dye or not should not alter the clinician's clinical behavior as dictated by the results of the ViziLite examination. The marking dye, when positive, acts as a lesion marker that allows for the removal of the ViziLite device while preserving the anatomic character of the lesion.**

ViziLite Blue Oral Exam PROCEDURE:

The ViziLite examination consists of visualization of leukoplakic areas using a diffuse chemiluminescent light source. Following conventional oral examination with incandescent light, there is a pre-exam rinse with ViziLite Rinse, activation of the ViziLite, with placement in the ViziLite Retractor, dimming of the ambient light and re-examination with ViziLite. Under ViziLite, atypical or dysplastic mucosal

abnormalities will appear bright white, distinctly demarcated, sharply marginated areas that contrast the surrounding non involved epithelium. Any lesion identified with ViziLite is further evaluated using the adjunctive ViziLite Blue Oral Lesion Identification and Marking System (pre and post acetic acid swabs and Tolonium Chloride stain swab).

PRINCIPLE OF ACTION:

ViziLite (OralLite):

Traditionally, following application of a cytoplasmic dehydration agent such as an acetic acid solution, acetowhite or leukoplakic lesions are seen with changes in refractile properties that occur in atypical nonkeratinized squamous epithelium due to an increased nuclear cytoplasmic ratio.

Adding diffuse chemiluminescent light (ViziLite (OralLite)/Speculite) to a conventional projected incandescent light exam has been clinically shown to increase the detection of biopsy proven squamous cell dysplasia and malignancy in squomous epithelium in the lower female genital tract when compared with detection by the naked eye and detection with magnified visualization with incandescent light.

This device has preiously been cleared for use as an adjunct to a conventional examination. (K 03995, K 012070)

ADVERSE EVENTS:
None Known.

CLINICAL STUDIES:

In IRB monitored clinical trials conducted at three University Hospital sites involving 86 adult patients with a history of leukoplakia and 92 biopsied lesions, the data continued to demonstrate that the ViziLite device made it easier for the examiner to see mucosal changes of leukoplakia and erythroleukoplakia when compared with projected incandescent light (as was demonstrated in K 003995). Thus, it appears that the ViziLite is a useful adjunct to help direct the examiner to lesions that would be difficult or poorly seen with incandescent light alone, but is non-specific with regard to underlying pathology.

The addition of the ViziLite Blue Oral Lesion Identification and Marking System using Tolonium Chloride dye retention by ViziLite-Identified acetowhite lesions provided additional information to the practitioner when examining patients at high risk for oral malignancy, particularly in patients with a prior history of squamous cell cancer or dysplasia. When the Tolonium Chloride dye marked the acetowhite lesions, the health care provider was able to remove the ViziLite

device from the patient's mouth and see the lesion with incandescent illumination. This was true whether the uptake of the stain had been diffuse (the entire lesion stains with the marker-dye) or the lesion had an irregular or stippled uptake. The provider has the ability to choose to study these lesions with the aid of loupes, to futher determine lesion characteristics, or use the now freed up hand to perform a biopsy.

The usefulness of this adjunctive approach to lesions seen with the ViziLite device is in the assisting the practitioner in his/her decision to immediately bipsy (or refer for biopsy) an acetowhite lesion seen with ViziLite or deferring a definitive biopsy in favor of following the lesion using standard clinical observation techniques.

CONTRAINDICATIONS:

The ViziLite (OralLite) examination is an adjunct to conventional oral examination with incandescent light and should not be used without first performing a conventional examination.

The ViziLite Blue Oral Lesion Identification and Marking System (with Tolonium chloride) is not intended to be used without prior traditional oral visual examination using ambient projected light followed by ViziLite (OralLite) examination.

The ViziLite Blue Oral Lesion Identification and Marking System (with Tolonium chloride) is not intended for "initial identification" of abnormalities of the oral mucosa, but is provided to the health care professional as an adjunct to the already cleared Vizilite (OralLite) examination for the evaluation, monitoring, and sampling of "Vizilite-Identified lesions" in patients identified as high-risk for oral cancer.

The ViziLite Blue Oral Lesion Identification and Marking System (with Tolonium chloride) is contraindicated in patients with a known history or hypersensitivity to any of the ingredients or their analogs.

The ViziLite Blue Oral Lesion Identification and Marking System (with Tolonium chloride) is contraindicated in patients who are pregnant or lactating.

Due to the lack of safety data, The ViziLite Blue Oral Lesion Identification and Marking System (with Tolonium chloride) should not be used in children, patients with liver or renal insufficiency, or patients with difficulty swallowing.

The ViziLite Blue Oral Lesion Identification and Marking System (with Tolonium chloride) should be used with caution in patients who may have difficulty

following directions during the lesion staining procedure (e.g. patients with severe physical or mental disabilities).

WARNING/PRECAUTIONS – ViziLite

To prevent swallowing or choking:
The health care provider should ensure that the activated ViziLite is firmly inserted into the provided ViziLite (OralLite) Retractor before placing it into the patient's mouth.

The health care provider should hold firmly onto the ViziLite Retractor while it is placed inside the patient's mouth.

To prevent potential leakage of ViziLite chemicals into the mouth:
Insect the ViziLite (OralLite) for any evidence of chemical leakage prior to capsule activation. Discard any capsule that does not appear to be intact.

Inspect the activated ViziLite (OralLite) for potential leakage before placing it into the patient's mouth for ViziLite (OralLite).
Do not use a capsule for ViziLite (OralLite) if the capsule does not appear to be intact or functioning properly.
[**Note:** The chemiluminescent chemicals and the materials used in the manufacturer of the ViziLite (OralLite) have been shown to be non-toxic in animal studies should they be either swallowed or applied to the epithelial surface. Therefore, the ViziLite (OralLite) should not present a significant risk to humans when used as a light source for oral examination under usual conditions. However, oral exposure to the contents of the ViziLite (OralLite) may cause transient irritation to the mouth, throat and gastrointestinal tract.]

[**Remedy for accidental exposure to chemicals:** Rinse mouth immediately and dilute with 4 to 8 ounces of milk or water. Decontamination with syrup of ipecac, activated charcoal or gastric lavage is not indicated.]

After 10 minutes the chemiluminescent light begins to fade and the ability to visualize white lesions will also decrease. Therefore, perform the examination of oral tissues within 10 minutes of ViziLite (OralLite) activation.

ViziLite (OralLite) is to be used as an adjunct to conventional oral examination. ViziLite (OralLite) is not intended to be used for grading acetowhite lesions.

All activated and/or used ViziLite's (OralLite) must be discarded in a proper receptacle per the procedures of the facility.

ViziLite (OralLite) is intended as a disposal, single use patient device.

ViziLite (OralLite) is not reusable.

WARNINGS/PRECAUTIONS – ViziLite (OralLite) Rinse
ViziLite (OralLite) is intended as a disposal, single use patient device.

ViziLite (OralLite) is not reusable.

ViziLite (OralLite) Rinse is not intended to be swallowed.

ViziLite (OralLite) Rinse is intended for oral use only. Keep out of reach of children.

Do not refrigerate ViziLite (OralLite) Rinse.

WARNINGS/PRECAUTIONS – The ViziLite Blue Oral Lesion Identification and Marking System

No severe adverse reactions are expected when The ViziLite Blue Oral Lesion Identification and Marking System (with Tolonium chloride) is used according to package instructions. Some patients may find the taste of the product unappealing and may gag. Patients may also experience a slight burning sensation of the oral mucosa due to the acetic acid.

Removal oral prosthesis should be removed and any associated trauma or inflammation given time to heal prior to use of the product.

Patients should be informed prior to the ViziLite Blue Oral Lesion Identification and Marking procedure that there may be a residual bluish discoloration on the vermillion border, dorsum of the tongue, and dental plaque, which usually wears off in 4-6 hours. Staining in these areas with Tolonium chloride is normal and should not be considered a positive result in the absence of clinical suspicion.

Care should be taken to protect clothing, as well as equipment and environmental surfaces from being stained. The patient should be advised of the possibility of this effect, and assured that the color change is temporary. The patient may also be instructed to contact his/her examining physician/dentist if this occurs.

Should any of the material be accidentally swallowed, the urine and and/or stools may be colored temporarily blue-green or blue, respectively. The patient should be advised of the possibility of this effect, and assured that the color change is temporary. The patient may also be instructed to contact his/her examining physician/dentist if this occurs.

Common restorative materials including porcelain, composites, and acrylics are not known to stain permanently.

INTERACTIONS

Interactions of the ViziLite Blue Oral Lesion and Identification Marking System components with other medications have not been studied, but are unlikely.

PREGNANCY AND LACTATION

The ViziLite Blue Oral Lesion Identification and Marking System is contraindicated for use for pregnant women. There have been no well-controlled studies in pregnant women to know the safety of use in this population.

The ViziLite Blue Oral Lesion Identification and Marking System is contraindicated for lactating women. It is not known whether Tolonium chloride is excreted in human breast milk.

OVERDOSAGE

No adverse events have been reported in the published literature concerning the use of Tolonium chloride in the mouth for staining oral lesions. The ViziLite Blue Oral Lesion Identification and Marking System contains a Tolonium chloride dye swab with **7mg of tolonium chloride**, which conservatively yields an exposure of approximately 0.1mg/kg (based on a 60kg person). Reports from published studies indicate physiological alterations are not observed at dose levels below 5 mg/kg administered intravenously. Some patients receiving 100 mg commercially available tolonium chloride orally in capsule from three times daily reported nausea. The **NOAEL** (No-Observable-Adverse-Effect Level) determined in toxicology studies or orally administered tolonium chloride was 20 mg/kg in rats and was 15mg/kg in rabbits. Data regarding Tolonium chloride and toluidine blue toxicity are summarized in Appendix A. Additional toxicology data for this product, beyond the data furnished in the Appendix, are available upon request.

Recommended Storage Conditions

Store between 15°C and 25°C (59°F - 77°F)

ViziLite (OralLite), when used in combination with conventional visual oral mucosal examination by health care providers, improved identification, evaluation, and monitoring of oral mucosal abnormalities in a population at increased risk for oral cancer.

The ViziLite-Blue Oral Lesion Identification and Marking System (with Tolonium chloride) can allow the examiner to continue to visualize oral mucosal lesions using incandescent (conventional projected)light, even after the ViziLite (OralLite) and its holder are removed from the oral cavity. This allows the examiner to measure the lesion size, observe the lesions borders, and obtain an appropriate tissue sample (biopsy) when clinically indicated.